Pulse Oximeter
Instruction
Manual

Ver.1.0

Contents

CHAPTER 1 Introduction

1.1 Brief Introduction

Thank you for purchasing the handheld pulse oximeter. The main functions of the device include SpO_2 and PR measure, visual and audio alarm, sensor off alarm, data storage and replay etc. Please read the operator's manual carefully before using it.

Note: The illustrations used in this manual may differ slightly from the appearance of the actual product.

1.2 Safety Information

Conception of Warning, Precaution and Notice

The Warning, precaution and Notice in this document are special information in favor of users operation.

★ Warning

Indicate that maybe some potential hurt or damage to patients.

★ Precaution

Make user take a serious attitude toward the incorrect operation, which are likely to incur some life-threatening incidents.

★ Notice

Serve as a pivotal notice to avoid preventable incidents during application of this equipment.

Warnings:

- The handheld pulse oximeter should be confined to sophisticated operator exclusively. Prior to application, we strongly suggest you should follow instructions listed in this document, or any wrong-doing operation which causes serious damage will take full responsibility for this. Our company will assume no warranty for using this equipment improperly.

- Do not close to liable flammable matters, spark in case of unexpected explosion.

- Do not apply this equipment at such environment as magnetic resonance imaging (MR or MRI) equipment which is the source of some electric noise to influence the accuracy of this equipment and following treatment.

- Make sure to apply this equipment for medial scope, and measurement results only serve as a reference for any relevant treatment.

- Please cautiously use this equipment for long time, and It is necessary for you to protect yourself from avoidable injury.

- When placing sensor in right place, please abide by work instructions strictly, for example do not extend tape or fix it too tightly.

- When beginning to measure associated body features please follow the doctor's counseling.

- When link this equipment to other peripherals, make sure you are sophisticated operator to handle this device. Any peripherals should be in the light of protocol of IEC 950 and IEC 601-1-1. Any input/output device should be following the protocol of IEC 601-1-1.

- Please strictly follow the sensor application instructions, considering the sensor is a sensitive device.

- The malfunction of sensor may cause inaccurate data which serve as a foundation to treat patients, so please make sure to pay more attention to the sensor and inspect it frequently.

- The worn-out data cables may cause inaccurate data and be used as a reference to treat patient, so please pay attention to data cable and check it frequently.

- The disposable peripheral should not be repeatedly used.

Precautions

- Rinsing the sensors with ethylene oxide solution may have adverse influence on the machine, Apart from this, the sensor should not be autoclaved or submerged.

- This device is intended for use by persons trained in professional health care. The operator must be thoroughly familiar with the information in this manual before using the device.

- Unplug the sensor from the monitor before cleaning or disinfecting to avoid the damage to the device and user.

- Alarm must be set up according to different situation of individual patient. Make sure that chime sound can be activated when alarm function begin to work.

Notices

- Application of this device may influence the measuring accuracy in the background of electromagnetic areas such as electro-surgery environment.

- Operation of this device may be adversely affected in the presence of computed tomography (CT) equipment. Use only the appointed sensors. Use of sensors not intended for use with this device may cause inaccurate

readings. Pay more attention to the application when applying this device under the situation of computed tomography (CT) environment.

- SpO_2 measurements may be adversely affected in the presence of high ambient light. Shield the sensor area (with a surgical towel, for example) if necessary.

- Dyes introduced into the bloodstream, such as methylene blue, indocyanine green, indigo carmine, and fluorescein, may adversely affect the accuracy of the SpO_2 reading.

- Any condition that restricts blood flow, such as use of a blood pressure cuff or extremes in systemic vascular resistance, may cause a failure to determine accurate pulse rate and SpO_2 readings.

- Remove fingernail polish or artificial fingernails before applying SpO_2 sensors. Fingernail polish or artificial fingernails may lead to inaccurate SpO_2 readings.

- SpO_2 average is the number of pulse beats over which the SpO_2 value is averaged; pulse average is the number of seconds over which the pulse value is averaged.

- Hazards arising from software errors have been minimized. Hazard analysis conforms to meet ISO14971: 2000 and EN60601-1-4: 1996. Significant levels of dysfunctional hemoglobins, such as carboxy-hemoglobin or methemoglobin, will affect of the accuracy of the SpO_2 measurement.

- Optical cross-talk can occur when two or more sensors are located in adjoining area. It can be eliminated by covering each site with opaque material. Optical cross-talk may adversely affect the accuracy of the SpO_2 readings.

- Change new batteries in time, when the power low indicator appears. As, the readings will influenced when the power is low.

- Obstructions or dirt on the sensor's red light or detector may cause a sensor failure. Make sure there are no obstructions and the sensor is clean.

- For routine equipment maintenance, please refer to the service procedures at the associated section as indicated in the manual.

- As to the other concerns for attention, please carefully look through the specific chapter in this instruction.

1.3 Intended Use

The purpose and function of the handheld pulse oximeter is to indicate measure and display the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults and pediatric patients in hospital, ambulatory, home, and EMS (emergency medical service) environments. The pulse oximeter is intended for spot-checking these levels and not indicated for continuous monitoring. It can assist the clinician diagnostically by quickly displaying the patient's SpO_2% and pulse rate and can additionally store 72 hours of data.

1.4 Electromagnetic Interference

This oximeter is designed and tested in compliance with the EMC standard, complying with the international standard for the EMC of the electronic medical device - IEC 60601-1-2. However, because of the proliferation of radio frequency transmitting equipment and other sources of electrical noise in the health-care and home environments (e.g. cellular phones, mobile two-way radios, electrical appliances) it is possible that high levels of such interference due to close proximity or strength of a source, may result in disruption of performance of this device.

This apparatus complies with the IEC 60601-1-2 international standard. The requirements of this international standard are: CISPR11, GROP1, and CLASS B

1.5 Equipment Classification

Classification according to IEC-60601-1	
According to the type of protection against Electrical shock:	Internal electrical power source equipment
According to the degree of protection against Electrical shock:	Type B equipment
According to the degree of protection against harmful ingress of water	Ordinary equipment (enclosed equipment without protection against ingress of water)
According to the methods of sterilization or disinfection:	Non-sterilizable: Use of Liquid surface disinfectants only.
According to the mode of operation:	Continuous operation
Equipment not suitable for use in the presence of a flammable anesthetic mixture air or with oxygen or nitrous oxide	

CHAPTER 2 General Descriptions

The handheld pulse oximeter adopts 1.5 inch CSTN screen. It can display the SpO_2，pulse rate value and all kinds of parameters, such as time, ID number, pulse bar,battery status and so on.

2.1 Front Panel & Displaying

Fig.1

Description of Fig.1：

1: Double-functional socket：for SpO_2% probe and data transfer socket.

   -Oximeter probe socket: Connect the probe with the oximeter before taking a measurement.

   -Data transfer socket: Connect the oximeter with PC by a USB data cable for transferring data recorded to PC.

2: ▲ the **UP** button: Select the different item, and adjust parameters. While in adjustment, press the **UP** button repeatedly to increase a parameter by one increment.

3: ⟲ the **ENTER & OK** button: Press this button to enter the selected menu or submenu, confirm your selection or return to the main menu.

4: ⟳ the **POWER** button: Press this button for about 3s to turn the oximeter on, and 4s to turn it off.

5: ▼ the **DOWN** button: Select the different item, and adjust parameters. Press the **DOWN** button repeatedly to decrease the parameter by one when adjustment.

6: Display screen (refer to Fig.2)
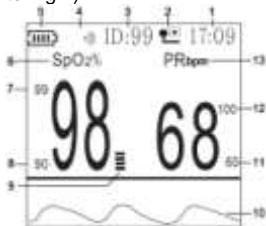
Fig.2

Description of Fig.2:

1: Time display in 24-hour format. The current time is 17:09 in Fig.2.

2:🔌:SpO₂ sensor connected indicator.

The indicator will not be shown if the SpO₂ sensor is disconnected from the unit.

3: ID:99: The ID number indicator.

If you set "Display" in "User ID Set" menu on, the user ID number will be shown on the top middle of screen(refer to Fig.2). Or else, it won't be shown (refer to Fig.15).

4: 🔊: Beep and alarm are on . ^z_z: Beep and alarm are off. 🔊:Beep is on while alarm is off.   🔔: Alarm is on while beep is off.

5:🔋: Battery power indicator. (See *battery life and replacement*.)

6: SpO₂% It is SpO₂ area of display below the indication.

◆It shows the oxygen saturation level of functional hemoglobin during normal measurement. The measured SpO₂ in Fig.2 is 98%.

◆The background color of the SpO₂ value shows red when the SpO₂ is outside the alarm limits.

◆It shows two dashes throughout probe off and finger out conditions.

7. SpO₂% upper alarm limit indicator.

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8. SpO$_2$% lower alarm limit indicator.

9. Pulse amplitude bar.

It indicates the dynamic pulse amplitude and rate. As the detected pulse becomes stronger, more bars light with each pulse. The reverse is true for weak pulses.

10. SpO$_2$ waveform display area.

◆It shows the SpO$_2$ waveform during normal measurement.

◆It shows "Probe Off" in probe-off condition.

◆It shows "Finger Out" in finger-out condition.

11. PR lower alarm limit indicator.

12. PR upper alarm limit indicator.

Note: If you set "Display" in "Alarm Set" menu "On", SpO$_2$% upper & lower alarm limit values and PR upper & lower alarm limit values will be shown on the screen (refer to Fig.2). If you set it off, all the alarm limit indicators will not be shown (refer to Fig.35).

13. **PR** bpm: it is PR area of display below the indication.

◆It shows the pulse rate in beats per minute during normal measurement. The measured PR in Fig.2 is 68 bpm.

◆The background color of the PR value shows red when the PR is outside the alarm limits.

◆It shows three dashes throughout probe off and finger out conditions.

2.2 Rear Panel

Fig.3

2.3 Product Features

◇ Compact, lightweight design for simple, one-hand operation
◇ Color LCD with adjustable backlight display SpO$_2$, pulse rate and pulse bar.
◇ Up to 99 patient ID and 72-hour record storage, visual & audio alarm, low battery alarm
◇ Data transfer to PC for storage or printing.
◇ Two AA size alkaline batteries
◇ Suitable for adult, pediatric and neonatal patient

Notice:

● To transfer data to PC, the oximeter need to be registered. As for detailed setup and operation, please refer to the "MedView" instruction manual.
● Transmission software and data cable are not standard accessories. Contact your local dealer for purchase.

CHAPTER 3 Install the Batteries and the Sensor

3.1 Install the Batteries

Fig.4

Description of Fig.4:
- ◆ (1): Fixing hole
- ◆ (2): Battery box
- ◆ (3): Battery box cover
- ◆ (4): Clasp

1）Push as direction as indicated by arrow marked and then open the cover with nail.

2) Install two batteries lightly as indicated by the polarity sign.

Note: Make sure the polarity of the batteries is correct.

3) Make the clasp into fixing hole and push as converse direction as arrow marked until the cover is closed.

Battery life and replacement

There are five shapes of the indicator: the centre with 4 bars (full), 3 bars, 2 bars,1 bar, empty and the frame in red. That the frame of indicator become red means few of battery capacity remains, and you should replace the batteries with new ones timely. Or else, the indicator displays with a red frame constantly until battery capacity reaches critical condition(the battery voltage is 2.4V±0.2V) at which time the unit shuts down.

Note: Always turn the unit off before replacing the batteries.

Warning!

If battery fluid should get in your eyes, immediately rinse with plenty of clean water. And then consult a doctor immediately.

Cautions!

$\diamond$ Do not use batteries not specified for this unit.

$\diamond$ Do not insert the batteries with the polarities in the wrong direction.

$\diamond$ Do not dispose of batteries in fire.

$\diamond$ If battery fluid should get on your skin or clothing, immediately rinse with plenty of clean water.

$\diamond$ Remove the batteries from this unit when you are not going to use it for a long period of time (approximately three month or more).

$\diamond$ Do not use batteries of a different type together.

$\diamond$ Do not use new and used batteries together.

$\diamond$ Dispose of the used batteries according to the applicable local regulations.

3.2 Install the Sensor
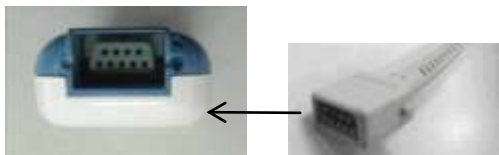
Fig.5

Insert the SpO$_2$ sensor to the socket (refer to Fig.5). Then SpO$_2$ sensor connected indicator 📟 will be shown on the display (refer to Fig.2). The indicator will not be shown if the SpO$_2$ sensor is disconnected from the unit.

CHAPTER 4 Setting ID, Date and Time

Always set the date and time before using the unit for the first time. Set different ID numbers for different users.

Check whether the date and time are correct before using the unit, reset them if necessary. The date and time are important indicators when a measurement is taken.

4.1 Date & Time Setting

Set the correct time according to the following steps:

1) Long press the **POWER** button to power on the oximeter, and then press the **ENTER** button to enter into the main menu refer to the fig.6.

2) Then press the **UP** button or the **DOWN** button to select "2.Time set" item, and then press the **ENTER** button to enter into the time setting menu refer to Fig.7.
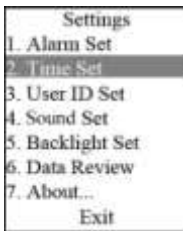
Settings	Settings
1. Alarm Set	1. Alarm Set
2. Time Set	2. Time Set
3. User ID Set	3. User ID Set
4. Sound Set	Time Set
5. Backlight Set	Time: 13 50 29
6. Data Review	Date: 2008- 04- 28
7. About...	
Exit	Exit
Fig.6	Fig.7

3) Hour setting

Press the **ENTER** button to make the number in the cursor highlight, and then press the **UP** button or the **DOWN** button to increase or decrease the time (refer to the fig.8). After setting the hour, press the **ENTER** button again to make the number in the cursor turns black, and then press the **UP** button or the **DOWN** button to select other item to set.

Settings	Settings
1. Alarm Set	1. Alarm Set
2. Time Set	2. Time Set
3. User ID Set	3. User ID Set
Time Set	Time Set
Time: 13 50 29	Time: 13 50 29
Date: 2008- 04- 28	Date: 2008- 04- 28
Exit	Exit
Fig.8	Fig.9

4) Minute setting

Press the **UP** button or the **DOWN** button to select the minute item, and press the **ENTER** button to make the number highlighted, Press the **UP** button or the **DOWN** button to change the minute. Refer to Fig.10 and Fig.11.

Settings	Settings
1. Alarm Set	1. Alarm Set
2. Time Set	2. Time Set
3. User ID Set	3. User ID Set
Time Set	Time Set
Time: 13:50 29	Time: 13:50 29
Date: 2008-04-28	Date: 2008-04-28
Exit	Exit
Fig.10	Fig.11

According to the "Hour setting" and the "Minute setting", you can set the Second, the Year, the Month, and the Day.

4.2 ID Number Setting

Press the **UP** button or the **DOWN** button in the main menu to select the "3. User ID Set". Refer to Fig.12.

Press the **ENTER** button, you can enter into the ID setting submenu as Fig.13.

Press the **ENTER** button to make the ID number highlighted, and then press the **UP** button or the **DOWN** button to increase or decrease the ID number, and finally press the **ENTER** button to confirm your settings. The range of ID number is: 1-99.

Settings	Settings	Settings
1. Alarm Set	1. Alarm Set	1. Alarm Set
2. Time Set	2. Time Set	2. Time Set
3. User ID Set	3. User ID Set	3. User ID Set
4. Sound Set	User ID	User ID
5. Backlight Set	ID Set: 99	ID Set: 99
6. Data Review	Display On	Display On
7. About...		
Exit	Exit	Exit
Fig.12	Fig. 13	Fig. 14
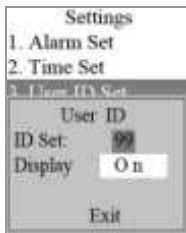
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If you set "Display" on, the user ID number will be shown on the top middle of screen. Or else, it won't be indicated (refer to Fig.16).
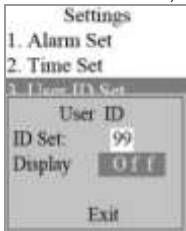
Fig.15
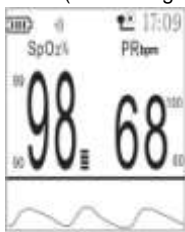
Fig.16

CHAPTER 5 Take a Measurement

After finishing the time and the ID number settings, plug your finger into the sensor shown as the following illustration:
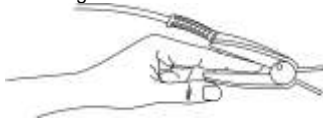
Fig.16 Placement of the sensor

- Select the suitable sensor in terms of type and dimension.
- Clip the sensor to the rational position of the patient finger.
- Plug sensor into SpO_2 port on top panel of pulse oximeter.

Note：**If the finger is not in the sensor, "Finger Out" will be shown on the bottom of the screen.**

Warnings!

- **The measurement would not be performed if the following instances come across in operation:**
  - ✧ Shock
  - ✧ Low temperature of hand
  - ✧ Have taken vascular activity medicine
  - ✧ Anemia
  - ✧ carboxyhemoglobin
  - ✧ methemoglobin
  - ✧ methylene blue
  - ✧ Indigo carmine

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- Use only SpO_2 sensors provided by the manufacturer for SpO_2 measurements. Other SpO_2 sensors may cause improper performance.

- **Do not use a SpO_2 sensor with exposed optical components.**

- **Excessive patient movement may cause inaccurate measurements.**

- Tissue damage can be caused by incorrect application or use of sensor, for example by wrapping the sensor too tightly. Inspect the sensor site to ensure skin integrity and correct positioning and adhesion of the sensor. More frequently inspection should be taken depend on different patients if necessary.

- Set the upper limit of SpO_2 alarm to 100% means cut off the upper alarm. High density of oxygen will cause adverse affection to the neonate .So the upper limit of SpO_2 alarm must be selected prudently according to the acknowledged clinical practice.

- **Inaccurate measurements may be caused by:**
    - ✧   Incorrect sensor application or use
    - ✧   Significant levels of dysfunctional hemoglobins (such as c arboxyhemoglobin or methemoglobin)
    - ✧   Intravascular dyes such as indocyanine green or methylene blue
    - ✧   Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
    - ✧   High-frequency electro surgical interference and defibrillators
    - ✧   Venous pulsations
    - ✧   Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
    - ✧   The patient has hypotension, severe vasoconstriction, severe anemia, or hypothermia
    - ✧   There is arterial occlusion proximal to the sensor
    - ✧   The patient is in cardiac arrest or is in shock

- **Loss of pulse signal can occur in any of the following situations:**
    - ✧   The sensor is too tight
    - ✧   There is excessive illumination from light sources such as a surgical lamp, a bilirubin lamp, or sunlight
    - ✧   A blood pressure cuff is inflated on the same extremity as the one to which an SpO_2 sensor is attached

Note：Pulse sensor should obviate the light source, e.g. radial lamp or infrared lamp.

CHAPTER 6 Other Settings

6.1 Alarm Setting

Press the **ENTER** button to enter into the main menu and the "1. Alarm Set" item is selected automatically, and then press the **ENTER** button to enter into the Alarm Set submenu.

1) SpO_2 alarm setup

After you enter into the "Alarm Set", the highlimit value below SpO_2 item is selected automatically (refer to Fig.17), and then press the **ENTER** button to highlight the value (refer to Fig.18). Press the **UP** button or the **DOWN** button to adjust the value, and then press the **ENTER** button to finish the setup of SpO_2% upper alarm limit. The range of upper limit is 70-99.

| Fig.17 | Fig.18 |

In the Alarm Set submenu, press the **UP** button or the **DOWN** button to select the lowlimit value below SpO_2 item(refer to Fig.19), and then press the **ENTER** button to highlight the value(refer to Fig.20). Press the **UP** button or the **DOWN** button to adjust the value, and then press the **ENTER** button to finish the setup of SpO_2% lower alarm limit. The range of lower limit is 69-98.

| Fig.19 | Fig.20 |

2) PR alarm setup

In the Alarm Set submenu,you can press the **UP** button or the **DOWN** button to select the highlimit value below PR item (refer to Fig.21), and then press the **ENTER** button to highlight the value (refer to Fig.22). Press the **UP** button or the **DOWN** button to adjust the value, and then press the **ENTER** button to finish the setup of PR upper alarm limit. The range of upper limit is 31-235.

Settings		Settings	
1 Alarm Set		1 Alarm Set	
2. Time Set		2. Time Set	
3. User ID Set		3. User ID Set	
Alarm Set SpO2 PR		Alarm Set SpO2 PR	
HighLimit 98 **100**		HighLimit 98 **100**	
LowLimit 90 60		LowLimit 90 60	
Default-set		Default-set	
Display O n		Display O n	
Exit		Exit	
Fig.21		Fig.22	

In the Alarm Set submenu, you can press the **UP** button or the **DOWN** button to select the lowlimit value below PR item (refer to Fig.23), and then press the **ENTER** button to highlight the value (refer to Fig.24). Press the **UP** button or the **DOWN** button to adjust the value, and then press the **ENTER** button to finish the setup of PR lower alarm limit. The range of lower limit is 30-234.

Settings		Settings	
1 Alarm Set		1 Alarm Set	
2. Time Set		2. Time Set	
3. User ID Set		3. User ID Set	
Alarm Set SpO2 PR		Alarm Set SpO2 PR	
HighLimit 98 100		HighLimit 98 100	
LowLimit 90 **60**		LowLimit 90 **60**	
Default-set		Default-set	
Display O n		Display O n	
Exit		Exit	
Fig.23		Fig.24	

3) Default-set

In the Alarm Set submenu,you can press the **UP** button or the **DOWN** button to select the Default-set item(refer to Fig.25), and then press the **ENTER** button to confirm the selection, synchronously returning to the main menu. The default limits are displayed on the measuring screen (refer to fig.26).

Fig.25   Fig.26

3) Display setup

In the Alarm Set submenu, you can press the **UP** button or the **DOWN** button to select the Display item, and then press the **ENTER** button to highlight the value(refer to Fig.27). Press the **UP** button or the **DOWN** button to select On/Off, and then press the **ENTER** button to confirm the setup. If you set Display "on", SpO_2% upper & lower alarm limit value and PR upper & lower alarm limit value will be indicated in screen(refer to Fig.2). If you set it "off", all the alarm limit indicator will not be shown (refer to Fig.28).

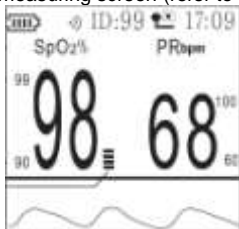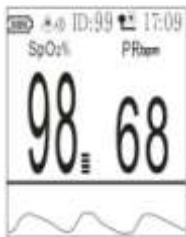Fig.27   Fig.28

In the Alarm Set submenu,you can press the **UP** button or the **DOWN** button to select the "Exit" item, and then press the **ENTER** button to return to the main menu.

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ALARM PRIORITY:

High priority: the highest level alarm, indicate the patient is in the very dangerous situation.

Medium priority: indicate the warning should be paid attention.

Low priority: indicate the measuring value beyond the preset limitation.

Alarm functions of the oximeter include technical and physiological alarms. All three priorities divided by built-in module and can not be changed by user.

VISUAL ALARMS:

If the alarm is activated through over limitation of physiological alarm, the background color of corresponding data area will turn red. If the alarm is activated by more than one physiological alarm, the background color of each parameter will turn red.

AUDIBLE ALARMS:

Audible alarms can be heard if there is no silence. The audible alarm has different tone pitch and on-off beep patterns for each alarm priority.
High priority: "Di-Di-Di---Di-Di……Di-Di-Di---Di-Di", beeps every 10 seconds.
Medium priority: "Di--Di--Di ", beeps every 15 seconds.
Low priority: " Di--", beeps every 20 seconds.

ALARM ACTION: *Alarms will be activated on following conditions:*

Physiological alarm:
The alarm will work when the SpO_2 value or pulse rate beyond the upper limit or goes below the lower limit. The background color of corresponding data area turns red. The difference is their priority; the SpO_2 has the high priority while the pulse rate has the medium.

Technical alarm:
The alarm will be sound in case of the finger out or probe off, and they are of low priority.

Warning!

If an alarm occurs, be sure to check patients' conditions immediately.

- Check which alarm is going on.
- Check patient's physiological condition.
- Find out the source of the alarm.
- Make the alarm mute if necessary.
- Check the alarm when no warning.

6.2 Sound Setting

In the main menu, press the **DOWN** button to select "4. Sound set" and then press the **ENTER** button to enter into the sound setup screen, refer to Fig.29 and the Fig.30.

| Settings |
| 1. Alarm Set |
| 2. Time Set |
| 3. User ID Set |
| 4. Sound Set |
| 5. Backlight Set |
| 6. Data Review |
| 7. About... |
| Exit |

| Settings |
| 1. Alarm Set |
| 2. Time Set |
| 3. User ID Set |
| Sound Set |
| Beep Set   Oll |
| Alarm Set   Off |
| Exit |

Fig.29   Fig.30

Press the **UP** button or the **DOWN** button to set the sound on or off, and then press the **Exit** button to return to the main menu.

$\sqrt[4]{}$: Beep and alarm are on.

$\overset{z}{z}$: Beep and alarm are off.

$\overset{)}{)}$: Beep is on while alarm is off.

$\overset{\blacksquare}{\downarrow}$: Alarm is on while beep is off.

6.3 Backlight Setup

In the main menu press the **DOWN** button to select the "5. Backlight Set" and then press the **ENTER** button to enter into the backlight setup screen. Press the **UP** button or the **DOWN** button to adjust the brightness. There are 5 levels. More bars shown means that backlight is brighter. And then press the **ENTER** button to return to the main menu. Refer to Fig.31 and Fig.32.

| Settings |
| 1. Alarm Set |
| 2. Time Set |
| 3. User ID Set |
| 4. Sound Set |
| 5. Backlight Set |
| 6. Data Review |
| 7. About... |
| Exit |

| Settings |
| 1. Alarm Set |
| 2. Time Set |
| 3. User ID Set |
| Backlight Set |
| Set: ▪▫▮▮▮ |

Fig.31   Fig.32

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6.4 Data Review

In the main menu press the **DOWN** button to select the "6. Data Review" and press the **ENTER** button to enter into the "Data Review" screen.   You can review the measurement records, refer to Fig.34. Press the **UP** button or the **DOWN** button to page up or page down by one page. Press the **ENTER** button to return to main menu.

Settings
1. Alarm Set
2. Time Set
3. User ID Set
4. Sound Set
5. Backlight Set
6. Data Review
7. About…
Exit

Time	SpO$_2$	PR	ID
18:16:35	98	70	99
18:16:31	98	72	99
18:16:27	98	70	99
18:16:23	98	84	99
18:16:19	98	76	99
18:16:15	98	74	99
18:16:11	98	71	99
Page:	18/18		

Fig.33   Fig.34

6.5 Other Information

In the main menu press the **DOWN** button to select the "7. About…" and press the **ENTER** button to enter into the screen as the Fig.36 shown. You can know the product version and remain storage spare room.

The oximeter can store 72 hours SpO$_2$% and Pulse rate data at most. The time interval is 4 seconds.

Settings
1. Alarm Set
2. Time Set
3. User ID Set
4. Sound Set
5. Backlight Set
6. Data Review
7. About…
Exit

Settings
1. Alarm Set
2. Time Set
3. User ID Set
Remain Storage
71H 53M 16S
MD300I2-1.0.1

Fig.35   Fig.36

Note: It will turn to the normal measuring screen if there is no operation for 30 seconds.

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CHAPTER 7 Maintenance and Repair

WARNING：The advanced digital circuit inside the oximeter does not require periodic calibration and maintenance, instead of replacing the batteries.

CAUTION: Don't open the cover of oximeter or repair electronic circuits. Openning the cover will cause the damage of the device and the annulment of the guarantee.

7.1 Maintenance

It is very important for user to make daily maintenance of oximeter and parts and it is the important guarantee for our company to perform maintenance service. If user did not do according to the below stipulation and lead to oximeter failure and possible health damage, our company is entitled to change guarantee time.

a）Should constitute effective maintenance plan for oximeter and reused supplies. This plan includes inspection and clearance and it must comply with the policy of epidemical control unit or health department.

b）Please take out battery before cleaning the oximter.

c）Should make regular clearance. (Must comply with the policy of epidemical control unit or health department) The appearance of oximeter can be cleared by not-denuded wet cloth. Please use the following permitted solution:

  Ammonia (diluted)
  Glutaraldehyde
  Javel bleacher (diluted)
  Mild soap water (diluted)

Please comply with the following regulations to avoid oximeter damage:
Comply with diluted solution advised by manufacturer all the time

Wipe up all clearance solution by dry cloth after clearance all the time.

Never use such cleanser with wax.

Never use or spurt any clearance solution on oximeter and permit liquid flow into the back of power supply, connector or any air channel in oximeter.

Never use the following cleanser:
  ○ Any kind of scrub solution or impregnant
  ○ Acet
  ○ Ketone , Lycine
  ○ Cleanser with alcohol

d）During operation please note:

After operation the oximeter, you should take off the probe and make daily maintenance. If you will not use it for a long time please take out battery.

e）Battery maintenance

Please take out battery if you will not use the oximeter for a long time.

Please charge the battery fully if you will not use it for a long time.

Please charge over 14 hours at first time, or will reduce the battery life.

If occurs any abnormal phenomena, you should stop using immediately and reuse after inspection by a technologist.

7.2 Calibration and Verification

The performance should be checked every year. It should also be checked after every maintenance and repair.

Required Test Equipment: SpO_2 signal Simulator

Note: The simulator cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter.

7.2.1 Control Key Verification.
Press Menu key, display the history data.

7.2.2 Sound Verification
a)．Set the oximeter sound ON.
b)．The simulated heart beep sound Can be heard.

7.2.3 SpO_2 & Pulse Rate Measurement Value Verification

a)．Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b)．Insert the operator's finger into the finger sensor, the SpO_2 measured value of a healthy person should be from 95% to 99%, and the pulse rate is same as heart rate,

c)．If SpO_2 Simulator is available, verify the accuracy of Oxygen Saturation Value with BCI probes as follows:

Oxygen Saturation	Tolerance
96%	±2%
86%	±2%
70%	±3%

7.2.4 SpO₂ & Pulse Rate Alarm Verification

a). Connect SpO_2 Probe to the SpO_2 connector on the oximeter.

b). Insert the operator's finger into the finger sensor, the SpO_2 measured value of a healthy person should be more than 96%.

c). Set the SpO_2 high limit as 90, low limit as 80.

d). Verify the SpO_2 visual and auditory alarms, the backgroud color of the SpO_2 data should be red and "dudu" voice should be heard.

7.3 Trouble Shooting

a) Can't power on the oximeter

Please check the batteries voltage and try to replace batteries. If you confirm that the batteries installed is in good status and the unit can't still power on, please contact with local customer service center.

b) "Probe OFF" alarm

Please check whether the probe was connected with the oximeter correctly. If the sensor is connected with extension cable please check whether the extension cable is connected with the sensor correctly.

7.4 Warranty and Repair

7.4.1 Maintenance Method

a）Maintenance responding time: 9:00am～17:30pm, Monday to Friday

b）Service support: Our company will offer user telephone and e-mail technology support and parts change.

Parts change: our company will change parts if it is necessary free of charge in the warranty period.

Because parts are the sources of maintenance, user should send them back to our company if not specified.

c）Update the system software free of charge.

7.4.2 Exemption and Limitation:

a) Our company isn't responsible for such damage caused by force nature. For example: fire, thunder flash, flood, cyclone, hail, earthquake, house collapse, commotion, plane failing and traffic accident, deliberate damage, lack of fuel or water, labor and capital bother, strike and stop-working etc.

b) No-service offer

No-service is covered for charges relating to the disassembling, refurbishing, repackaging and moving the monitor or the part of it.

The damage caused by the third company not commended by our company to adjust, install and replace the parts of the oximeter.

The damage and failure caused by user or its representative doesn't comply with the operator's manual

c) The oximeter is installed or connected with such external device without our company permission as printer, computer, internet line and lead to oximeter failure. Our company will charge for the maintenance.

d）Responsibility limitation

During the period of maintenance contract validity, if user changes the parts manufactured by other manufacturers without our company permission, our company is entitled to stop contract.

7.4.3 User Guarantee

a) Please read user manual carefully before operation

b) Please operate and make daily maintenance as request of manual and guarantee

c) Power supply and environment.

7.4.4 No-guarantee Principle

There is no-dispelled smut and not-original mark in the crust.

●There is physical damage on oximeter and its accessory.

●There are liquid leftover and eyewinker on oximeter and lead to short circuit and plugboard failure.

●All the probe and accessories belong to consumption and beyond free change range.

●Such damage of probe caused by mechanical force doesn't belong to free change range.

●During measurement of SpO_2, principle leads to measure value difficult or inaccurate measurement.

●Maintenance seal of oximeter are not opened.

●Not-original package lead to oximeter during transportation

●Not-professional person operation leads to oximeter failure. Not our
 company professionals or authorized personnel disassemble oximeter and
 lead to oximeter failure.

●Not carefully read manual and so wrong operation lead to oximeter damage
 and failure.

7.4.5 User's Special Request for Guarantee Time

Our guarantee constitution for oximeter complies with electronic product
after-sale service standard regulated by national laws. We regulate the
guarantee time of mainboard is one year and all the accessories are three
months. If users request the guarentee time beyond our regulated guarantee
time, we should take it into consideration. Because electronic product has
such character of quick changing, for such user asking more than three years
guarantee time, our company will not buy oximeter parts during maintenance.
Our company will upgrade oximeter or change new maintenance methods, for
this, we charge the lowest price for new oximeter with user permission.

7.4.6 Repackage

●Take all the accessories and put them into plastic cover

● Try to use original package and packing material. User will be responsible
 for such damage caused by bad package during transportation.

●Please offer guarantee list and copy of invoice to standby with the period of
 guarantee.

●Please describe failure phenomenon in detail and altogether offer oximeter.

7.5 Storage and Transportation

Storage：Storage Temperature -20°C～55°C，Relative Humidity 10％～93%

Transportation：Transport by airline, train or vessel after packing according to
request.

Package：We pack the product with the hard bag. We put the foam between
the inner box and the cartoon to alleviate the shake.

APPENDIX A Specifications

Notes:
- Specifications may be changed without prior notice.
- The circuit diagrams, the list of components, the illustration of diagrams, and the detailed rules of calibration, are provided exclusively to professional authorized by our company.

Display:
Data: SpO$_2$%, PR, pulse column
Data update time: 12s
Others: connection status of probe and other alarm information.

Alarm:
Alarm: SpO$_2$% and pulse rate value, probe off, finger out, battery exhausted
Alarm mode: audio alarm, visual alarm and information
Range: SpO$_2$: 69%-99%, PR: 30-235bpm
Default values: SpO$_2$: Upper 99%, lower 90%; PR: Upper 100, lower 60.

SpO$_2$%:
Display range: 0%~99%
Resolution: 1%
Accuracy: ±3% (70%-99%)   Unspecified (0-69%)

Probe LED Specifications

	Wavelength	Radiant Power
RED	660±2nm	1.8mW
IR	905±10nm	2.0mW

Pulse Rate:
Display range: 0~254bpm
Measurement range: 30~235bpm
Resolution: 1bpm
Accuracy: 30~99 ±2bpm; 100~235 ±2%

Operation Environment:
Operating temperature: 5℃～40 ℃
Relative humidity: 5％～80％，non-condensing
Atmosphere pressure: 86kPa～106kPa
Power supply: Two AA alkaline batteries
Working time: work for 30 hours continuously

Transport and Storage Environment:
Storage Temperature:　－20℃～55 ℃
Relative humidity:　10％～93%

Store and replay:
Store and replay 72 hours SpO$_2$% and Pulse rate value, the time interval is 4 seconds.

Accessories:

- **Standard accessories:**

    1. Two AA batteries

    2. One instruction manual

    3. One adult finger sensor: M-50E03CSO

- **Optional accessories:**

    1. Finger sensor for pediatric and infant: M-50C04CSO

       (Pediatric 15-45 Kg, Infant 3-15 Kg)

    2. Finger sensor for neonate: compatible with BCI (Neonate<3kg)

    3. USB data cable

    4. Software CD for data transmission.

APPENDIX B Declaration

Guidance and manufacture's declaration - electromagnetic immunity -for all EQUIPMENT and SYSTEMS

Guidance and manufacture s declaratioelectromagnetic immunity			
The *Handheld Pulse Oximeter* is intended for use in the electromagnetic environment specified below. The customer or the user of *Handheld Pulse Oximeter* should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compli ance level	Electromagnetic environment- guidance
Electrostat ic discharge (ESD) IEC 610004-2	6 kV contact 8 kV air	6 kV contact 8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.

Guidance and manufacture's declaration - electromagnetic immunity -for EQUIPMENT and SYSTEMS those are not LIFE-SUPPORTING

6100 0-4-6 Radiated RF IEC 6100 0-4-3	3 V/m 80 MHz to 2.5 GHz		$d = \frac{3.5}{V_1} \sqrt{P}$ 80 MHz to 800 MHz $d = \frac{3.5}{V_1} \sqrt{P}$ 800 MHz to 2.5 GHz Where$P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,ᵃ should be less than the compliance level in each frequency range.ᵇ Inter ference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1   At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2   These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorpt ion and reflection from structures, objects and people.

ᵃ   Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be p redicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the *Handheld Pulse Oximeter* is used exceeds the applicable RF compliance level above, the *Handheld Pulse Oximete*should be observed

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or YSTEM - for EQUIPMENT or SYSTEM that are not

LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the *Handheld Pulse Oximeter*		
The *Handheld Pulse Oximeter* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *MD300 Handheld Pulse Oximeter* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *Handheld Pulse Oximeter* as recommended below, according to the maximum output power of the communications equipment.		
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = \dfrac{3.5}{V_1}\sqrt{P}$	80 MHz to 800 MHz $d = \dfrac{3.5}{E_1}\sqrt{P}$	800 MHz to 2.5 GHz $d = \dfrac{7}{E_1}\sqrt{P}$

	0.1167	0.1167	0.2334
	0.3689	0.3689	0.7378
	1.1667	1.1667	2.3334
10	3.6893	3.6893	7.3786
100	11.6667	11.6667	23.3334

For transmitters rated at a maximum o utput power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1   At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2   These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.